



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097

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April 26, 2002

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Ref: 02-CIN-13188**

Joseph W. Goulet, Member/Owner  
Steltzer Farms Food Service, LLC  
911 Steltzer Rd.  
Columbus, OH 43219

Dear Mr. Goulet:

On March 26-28, 2002, we inspected your sandwich and salad manufacturing operation, located at the above address. This inspection found you have serious deviations from FDA's Fish and Fishery Products regulations (21 CFR Part 123). These deviations cause your tuna, breaded cod and pollock sandwiches, and tuna noodle casseroles to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find links to this Act and the Seafood HACCP regulations on FDA's website at [www.fda.gov](http://www.fda.gov).

The deviations observed are as follow:

- (1) Failure to implement and follow a written HACCP plan to comply with 21 CFR 123.6.
- (2) Failure to establish sanitation control procedures and monitoring, in accordance with 21 CFR 123.11. For example there are no procedures that will assure sanitary conditions relating to: (a) safety of water used in production areas; (b) prevention of cross-contamination; (c) protection of food from adulterants; (d) proper use, labeling and storage of toxic compounds; (e) control of employee health conditions; and (f) exclusion of pests.
- (3) Failure to adequately monitor employee practices to assure compliance with 21 CFR 123.11(b) in that employees were observed on multiple occasions returning from breaks without washing or sanitizing their hands before handling food products.

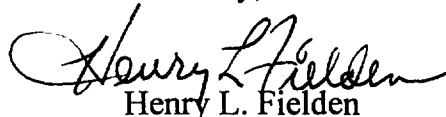
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation which would assist us in evaluating the adequacy of your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Charles S. Price, Compliance Officer, 6751 Steger Drive, Cincinnati, Ohio 45237-3097. If you have any questions regarding any issue in this letter, please contact Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

A handwritten signature in dark ink, appearing to read "Henry L. Fielden", with a large, stylized initial "H".

Henry L. Fielden  
District Director  
Cincinnati District